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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

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OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Nationwide Pilot Program Under FIFRA Section 2(ee)(6) Regarding Use of
Section 18 Emergency Exemption and Section 24(c) Special Local Need Products
in Indian Country – **DECISION MEMORANDUM**

FROM: James B. Gulliford
Assistant Administrator

A handwritten signature in black ink, which appears to read "James B. Gulliford", is written over the typed name and title.

THRU: OEX (1105A)

Marcus C. Peacock
Deputy Administrator (1102A)

TO: Stephen L. Johnson
The Administrator (1101A)

ISSUE

Should the Agency make, on a three-year pilot basis, a statutory finding under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 2(ee)(6), 7 U.S.C. §136(ee)(6), that it would be consistent with the purposes of FIFRA to allow registered pesticides to be used, within Indian country, for off-label uses that are available under section 18 emergency exemptions or section 24(c) special local need registrations?

OVERVIEW

Background

FIFRA section 18 provides that EPA may exempt any federal or state agency from any provision of FIFRA if EPA determines emergency conditions exist requiring such exemption. Pursuant to this authority, EPA has approved requests from states and federal agencies to allow sale, distribution and use of an unregistered pesticide or a registered pesticide for an unregistered use for a limited time (no longer than one year for specific public health exemptions or three years for quarantine exemptions). FIFRA section 24(c) authorizes states to issue registrations for additional uses of pesticide products currently registered under section 3 to meet special local needs.

FIFRA is silent on whether the benefits of these provisions are available to tribes and farmers in Indian country; therefore, tribes and farmers in Indian country do not explicitly have access to the full range of options available for addressing an emergency situation or special local need. This situation may present equity, enforcement and environmental protection concerns in Indian country.¹ This gap in our national protection could allow plant diseases or pest species to affect growers in Indian country and allow them to remain uncontrolled in areas proximal to major state agricultural centers.

EPA has interpreted emergency exemptions requested by a state and special local need registrations issued by a state as not extending to Indian country located within such a state. As a result, off-label use in Indian country of a registered pesticide in a manner authorized in a state under section 18 or registered by a state under section 24(c) would be considered a violation of FIFRA's general prohibition against the use of "any registered pesticide in a manner inconsistent with its labeling." [FIFRA §12(a)(2)(G), 7 U.S.C. § 136j(a)(2)(G).] The Tribal Pesticide Program Council (TPPC) and certain Indian tribes have requested EPA consider issues relating to access to FIFRA section 18 emergency exemptions and section 24(c) special local need registrations in Indian country.

FIFRA Section 2(ee)(6)

FIFRA section 2(ee)(6), 7 U.S.C. §136(ee)(6), authorizes the Administrator to allow use of a registered pesticide that might otherwise be considered inconsistent with the pesticide's labeling if he determines that use of the pesticide is "consistent with the purposes of FIFRA." In essence, with a section 2(ee)(6) finding in place, a use of a registered pesticide that would otherwise be considered a violation of FIFRA would be lawful, provided the conditions of the section 2(ee)(6) finding are met. Such a finding would be limited to registered pesticides and would not authorize the use, sale or distribution of unregistered pesticides.

2006-2007 Pilot Programs

To address concerns that areas of Indian country within a state may experience the same pest infestation problem that leads a state to request a section 18 exemption or to issue a section 24(c) registration, EPA implemented two pilot programs. The first was intended to make section 18 and section 24(c) pesticides for the control of soybean rust available for use in Indian country nationwide. To implement that pilot program, the Administrator made a statutory finding under section 2(ee)(6) that "Use within Indian country of products designed to control soybean rust which are available under section 18 or section 24(c) in counties encompassing or contiguous to that Indian country would be consistent with the purposes of FIFRA." This finding made it consistent with the purposes of FIFRA for growers in Indian country to use registered pesticides to address soybean rust just as growers in surrounding counties could, in situations where it was

¹ Indian country is defined at 18 U.S.C. § 1151 as: "(a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state, and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same."

determined that the requirements of section 18 or section 24(c) had been met in the encompassing or contiguous county and so long as the conditions of the finding were met.

The second pilot program focused on the Yakama Nation and Washington State. It was intended to address more generally (i.e., beyond just products designed to control soybean rust) the use within Yakama Indian country of products available outside Yakama Indian country under section 18 or section 24(c). To implement this pilot program, the Administrator made a statutory finding under section 2(ee)(6) that "Use, within Indian country associated with the Yakama Nation, of products available under section 18 or section 24(c) in counties of the State of Washington encompassing or contiguous to those lands would be consistent with the purposes of FIFRA." This pilot program was intended to allow EPA to work with a single tribe and state to assess the effectiveness and efficiency of the section 2(ee)(6) process in a wider context than soybean rust.

These pilot programs expired on December 31, 2007.

2006-2007 Pilot Programs Results and Other Supporting Information

The Yakama pilot program demonstrated to EPA there is need for making emergency exemption and special local need products available for use in Indian country. The soybean rust pilot program yielded more limited results. It provided no hard data because the original concern for potential widespread effects from the pest were not realized. However, some tribal members provided anecdotal information on how useful access to section 18 or section 24(c) products would be, should a major outbreak occur. The Yakama pilot had greater impact because it provided for use within Yakama Indian country of most of the emergency exemptions and special local need registrations then in place in Washington. Based on qualitative information EPA received from the state and the tribe, this pilot program appears to have been effective. However, the Yakama Nation has a long-standing relationship with Washington with respect to pesticide regulation, so a pre-existing process was in place for exchange of information and for establishing the need for and utility of emergency exemptions. This may not be the case for all tribes. Therefore, EPA's Office of Pesticide Programs (OPP) is seeking to extend this pilot program to gain experience on this approach nationwide.

Tribes were given the opportunity to communicate with EPA regarding any concerns before the pilot program began, which could have resulted in the exclusion of particular uses or areas of Indian country from the pilot programs. No such concerns were expressed to EPA. In addition, EPA worked closely with the Yakama Nation regarding the more general pilot program in Yakama Indian country. The tribe was very supportive of the section 2(ee)(6) pilot program, which was implemented successfully throughout the duration of the pilot.

In repeated discussions with the TPPC, the TPPC has supported the provision of a process making products subject to emergency exemptions available in Indian country. A review of the broad section 18 economic benefits completed in April 2005 concluded the section 18 program as a whole provided significant economic benefits to all growers and consumers.

Summary of Today's Action

In a continuation of our efforts to make section 18 and section 24(c) products equally available in relevant areas of Indian country, OPP would like to implement a nationwide, three-year pilot program to provide for the lawful use of those pesticides in areas of Indian country that are within the geographic boundaries of state(s) or county(ies) to which the emergency exemption or special local need registration pertains. To implement this pilot program, the Administrator would make a statutory finding under FIFRA section 2(ee)(6) that "where a use of a registered pesticide product is authorized under section 18 or section 24(c), it would be consistent with the purposes of FIFRA to allow that same use within those areas of Indian country that are within the geographic boundaries of the state(s) or county(ies) to which the emergency exemption or special local need registration pertains."

This finding would be time-limited and would allow use of the identified products in areas of Indian country covered by the finding, for no longer than three years from the date of the Administrator's signature on this finding. Enforcement of violations from use of these products in Indian country would be done by the EPA regions, with the cooperation of tribes where the tribes have cooperative agreements with EPA relating to enforcement. This approach would allow us to gain experience with a national plan in Indian country before determining how or whether we should make a permanent finding.

This pilot program was developed after long and careful consideration, in consultation with tribes, and with input from various stakeholders. EPA consulted with tribes regarding any concerns about the use of section 18 and section 24(c) pesticides in their Indian country. (For a summary of the consultation with tribes, see Stakeholder Involvement below.) If a tribe wishes to express concerns later in the course of this pilot program, the tribe may contact its EPA regional tribal pesticides coordinator.

This finding affects federally recognized tribes in states where additional uses of registered pesticides are authorized under section 18 or section 24(c) and in those states that may apply for section 18 emergency exemptions or grant section 24(c) registrations in the future. This finding does not allow the use of those pesticides that are classified as restricted-use products unless the applicator is certified to apply the pesticide in the jurisdiction where the pesticide is being applied; nor does it allow the use of unregistered pesticides.

IMPACTS

This pilot program would be a major step toward developing an approach to make emergency exemption and special local need products available in relevant areas of Indian country. The attached finding would provide for lawful use of registered section 18 and section 24(c) products in areas of Indian country that are within the geographic boundaries of the state(s) or county(ies) to which the emergency exemption or special local need registration pertains for the duration of the pilot program.

This pilot program does not impose any new requirements or revise any regulations. This action will not cause any adverse economic impacts or additional regulatory burden associated with the emergency exemption process or special local need registration process. Furthermore,

this pilot program is not intended to override applicable tribal law. Tribes wishing to limit or prohibit the use of certain products may, under their own laws, do so at their own discretion and may enforce those tribal laws to the extent of their own authorities.

The finding may not apply to certain areas of Indian country as a result of particular concerns identified through communication with individual tribes during the course of the pilot program. Those who intend to use emergency exemption or special local need pesticide products made available pursuant to this section 2(ee)(6) finding in Indian country, including all lands within the exterior boundaries of Indian reservations and other areas of Indian country, must verify their area has not been excluded from this finding². Users also must comply with applicable tribal laws or regulations that may impose other requirements with respect to particular pesticides or their use. Information about such tribal laws or regulations must be obtained from the pertinent tribe.

STAKEHOLDER INVOLVEMENT

Stakeholder input has been a critical component of the Agency's development of this pilot program. Consistent with the federal government's trust responsibility to federally recognized Indian tribes, EPA provided notice to all tribes of its development of this section 2(ee)(6) pilot program and provided opportunities for consultation on this pilot program. EPA also provided information to tribes through the TPPC, individual tribal representatives, and EPA regional tribal groups. EPA provided information to states through the State-FIFRA Issues Research and Evaluation Group.

About 16 tribes participated in two formal consultation calls. Apart from three tribes identified below, the tribes were generally supportive of the pilot program and of EPA's efforts to make section 18 and section 24(c) products available for use in Indian country. Following is a summary of certain specific issues raised regarding implementation of the program, including notice from the three tribes that do not wish to participate in the pilot program:

- **Allowing the use of Section 18 and 24(c) products across county and state boundaries** – Several tribes urged EPA to include flexibility within the pilot program to allow the use of these products throughout their Indian country, including across county and state borders, and not just within those portions of their lands that are located within the geographic bounds of the underlying emergency exemption or special local need registration. OPP considered this option but has determined to recommend proceeding with the current geographic limitation. EPA's review of the environmental risks of a section 18 application or a section 24(c) registration covers areas of Indian country within an affected county or state as long as the application or registration covers those areas, i.e., the risk assessments are geographically specific to the application or registration and the resultant risk conclusions cannot be extrapolated to areas beyond the application or registration. Conducting wider risk assessments covering additional areas of a tribe's Indian country outside the state(s) or county(ies) to which the section 18 application or section 24(c) registration pertains would require resources beyond those currently available for this pilot

² A list of Indian country areas excluded from this finding can be found on EPA's web site, <http://www.epa.gov/oppfead1/tribes/pilot-project.htm>.

program. OPP will evaluate this issue during implementation of the pilot program to assess the significance of any need for a wider geographic scope.

- **Ability to withdraw from the pilot program on a product-by-product basis** – Questions were raised about the pilot being an all-or-nothing program, and why tribes would not be able to exclude their lands from the use of individual products while remaining within the program generally. OPP considered the possibility of excluding areas of Indian country on a product- or use-specific basis. However, given the nationwide scope of this pilot program, the hundreds of products potentially at issue, and the more than 560 federally recognized tribes, we deemed this option unfeasible. OPP will evaluate this issue as the pilot program is implemented to determine the frequency of use- or product-specific tribal concerns.
- **Notifying tribes when an 18 or 24(c) is applied for or approved** – Several tribal representatives said they would like to be notified as section 18 and/or section 24(c) uses arise, and e-mail was suggested as an appropriate means to do so. OPP agrees with this suggestion. OPP will notify EPA regional tribal pesticide coordinators by e-mail, who will in turn notify the affected tribes in their regions. EPA is also providing information to tribes about existing web sites where they may obtain further details.
- **Three tribes do not want to participate** – EPA has received letters from three tribes that do not want to participate in the pilot program: the Pueblo of San Felipe, NM; the Hopi Tribe, AZ; and the Pueblo of Picuris, NM. The Hopi Tribe said that to date, it has not demonstrated a need for these products and does not anticipate a need for them in the foreseeable future. The Pueblo of San Felipe and the Pueblo of Picuris simply declined to participate. OPP will note on the relevant web site listed above that the Indian country of these three tribes is excluded from the pilot program.

INTERNAL REVIEW

The Office of General Counsel (OGC), the Office of Enforcement and Compliance Assurance (OECA), and the American Indian Environmental Office (AIEO) have reviewed the attached finding and concur with our request to establish the pilot program.

PEER REVIEW

There were no major scientific or technical products supporting this action as defined by the Agency's Peer Review Handbook; therefore, we did not submit any support documents for peer review.

PLAIN LANGUAGE

This document and its attachment have been composed and edited with the express intent to deliver a clear and concise message to our stakeholder community. Though legal in nature, the document reflects our best effort to make the activity understandable to the broadest audience.

EXTERNAL AGENCY REVIEW

There was no external agency review of this document.

OMB TRANSACTION

This action is not subject to review by the Office of Management and Budget (OMB) under E.O. 12866, and was not otherwise shared with OMB for informal review or informational purposes.

ANTICIPATED EXTERNAL REACTION

Interested audiences include federally recognized tribes, TPPC, state lead pesticide agencies, select federal agencies (for example, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service and the U.S. Department of the Interior's Bureau of Indian Affairs), and the Association of American Pesticide Control Officials. We expect each of these groups to be very supportive of this pilot program.

CONTACT

Should you or your staff have any questions, please contact Daniel Helfgott, Chief of the Government and International Services Branch, at (703) 308-8054 or helfgott.daniel@epa.gov.

RECOMMENDATION

We recommend you approve this pilot program.

Attachment

DECISION

After considering the issue and facts presented in this memo and its attachment, please indicate your decision by signing under the appropriate header.

Approved:

Marino Perazal for SLJ

Stephen L. Johnson, Administrator

Date: November 28, 2008

Disapproved:

Stephen L. Johnson, Administrator

Date: _____

**Administrator Finding Under
Section 2(ee)(6) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
Regarding Use of Section 18 Emergency Exemption and Section 24(c) Special Local Need
Products in Indian Country**

FINDING

Pursuant to the authority in FIFRA section 2(ee)(6), I find that where a use of a registered pesticide product is authorized under section 18 or section 24(c), it is consistent with the purposes of FIFRA to allow that same use within those areas of Indian country that are within the geographic boundaries of the state(s) or county(ies) to which the emergency exemption or special local need registration pertains so long as the area of Indian country is not excluded from this finding based on concerns communicated by the relevant tribe. This finding is limited to a three-year pilot program.

Sections 18 and 24(c) are intended to enable states to deal with local situations that are not provided for on existing EPA-approved labels. Congress has specifically stated the purpose of section 24(c) is "to give a State the opportunity to meet expeditiously . . . the problem of registering for local use a pesticide needed to treat a pest infestation that is a problem in the State but that is not sufficiently widespread to warrant the expense and difficulties of Federal registration." Federal Pesticide Act of 1978, U.S. Senate Committee on Agriculture, Nutrition, and Forestry, Committee Print, January 1979, p. 170. Areas of Indian country within a state may experience the same pest infestation problem that leads a state to request a section 18 exemption or to issue a section 24(c) registration.

EPA's review of section 18 emergency exemption requests and section 24(c) registrations focuses on risks to human health and the environment without regard to whether affected persons or environmental assets are located within or outside Indian country. This review thus includes areas of Indian country geographically located within a given county or state to which a section 18 or 24(c) use pertains. Pesticide users in Indian country who apply products made available through this section 2(ee)(6) finding will be required to follow the same use directions (*e.g.*, application rate, application interval, etc.) as users outside Indian country. Therefore, EPA's review of the environmental risks of a section 18 application or section 24(c) registration would apply equally to areas of Indian country within an affected county or state. If the additional use in Indian country adversely affects the risk concerns for the section 18 or section 24(c) products, those areas will be noted in EPA's action on the section 18 emergency exemption or section 24(c) registration.

ADDITIONAL CONSIDERATIONS

1. EPA consulted with tribes regarding any concerns about this pilot program. During this pre-pilot consultation period, three tribes expressed a desire to be excluded from the program through letters submitted to EPA by appropriate tribal representatives. The relevant areas of Indian country for these tribes have been identified on the web site designated below to provide information on the geographic scope of the pilot program. No other tribe expressed a

concern about being included in the program, which EPA believes indicates broad support for the availability in their Indian country of products subject to this finding. If a tribe wishes to express concerns later in the course of this pilot program or be withdrawn from the program, the tribe should contact the pesticide tribal coordinator in the appropriate EPA regional office listed below. This request should come from a tribal chairperson or other elected official or a tribal official authorized by the elected tribal leadership to represent the tribe. EPA will consider tribal requests not to participate in the pilot program only on a program-wide basis, and not on a product-by-product or use-specific basis. Any exclusions of Indian country areas from the pilot program will be effective once the area is listed on the web site described below.

EPA regional pesticide tribal coordinators:

Region 1	Mr. Robert Koethe U.S. EPA Region 1 1 Congress Street, Suite 1100 Mail Code SEP Boston, MA 02114 617-918-1535	Region 2	Mr. Adrian Enache U.S. EPA Region 2 USEPA Facilities, Raritan Depot 2890 Woodbridge Avenue Mail Code 500MS500 Edison, NJ 08837 732-321-6769
Region 4	Ms. Patricia Livingston U.S. EPA Region 4 61 Forsyth Street, S.W. Atlanta, GA 30303 404-562-9171	Region 5	Mr. Dan Hopkins U.S. EPA Region 5 77 West Jackson Boulevard Mail Code LC-8J Chicago, IL 60604 312-886-5994
Region 6	Mr. Gregory Weiler U.S. EPA Region 6 1445 Ross Avenue, Suite 1200 Mail Code 6PDP Dallas, TX 75202 214-665-7564	Region 7	Mr. Jamie Green U.S. EPA Region 7 901 North Fifth Street Mail Code WWPDTOPE Kansas City, KS 66101 913-551-7139
Region 8	Ms. Linda Himmelbauer U.S. EPA Region 8 1595 Wynkoop St. Mail Code 8P-P3T Denver, CO 80202 303-312-6020	Region 9	Ms. Pam Cooper U.S. EPA Region 9 75 Hawthorne Street Mail Code CED-5 San Francisco, CA 94105 415-947-4217
Region 10	Mr. Scott Downey U.S. EPA Region 10 1200 Sixth Avenue, Suite 900 Mail Code OCE-084 Seattle, WA 98101 206-553-0682		

2. Pesticide users in areas of Indian country within the geographic boundaries of the state(s) or county(ies) to which an emergency exemption or special local need registration pertains who intend to use pesticide products pursuant to this finding must obtain a copy of the label approved under section 18 or section 24(c) and comply in all respects with that label. Failure to comply fully with those directions would subject a user to possible action under FIFRA for use of a registered pesticide in a manner inconsistent with its label or labeling.

Those pesticide users must also verify lands within their area have not been excluded from this finding by checking the following EPA web site:
<http://www.epa.gov/oppfead1/tribes/pilot-project.htm>. Users are also responsible for complying with applicable tribal laws or regulations that may impose other requirements with respect to particular pesticides or their use. Such tribal laws or regulations may be enforced by the relevant tribes to the extent of their authorities.

3. Enforcement actions for violations from use of these products in Indian country under this finding will be done by the EPA regions with the cooperation of tribes that have entered into relevant cooperative agreements with EPA.

4. This finding is effective for up to three years from the date of the Administrator's signature.

5. This finding is contingent upon the determination that the section 18 and section 24(c) uses will not increase the risks associated with the pesticides. If the additional use in Indian country adversely affects the risk concerns for the section 18 or section 24(c) products, the finding will not apply in those areas and they will be noted in EPA's action on the section 18 emergency exemption or section 24(c) registration.

6. This finding does not allow the use of pesticides that are classified as restricted-use products unless the applicator is certified to apply the pesticide in the jurisdiction where the pesticide is being applied.

7. This finding is limited to FIFRA Section 18 and 24(c) products that are based on registered pesticides and does not authorize the use within Indian country of any unregistered pesticide. Thus, an unregistered pesticide available under section 18 for use in a state or county outside of Indian country will not be available for use in Indian country under this finding.